

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION <i>APPLIES TO ALL CASES</i>	Case No. 1:17-MD-2804 Hon. Dan A. Polster <u>FILED UNDER SEAL</u>
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**PLAINTIFFS’ REPLY TO CARDINAL HEALTH’S OBJECTION
TO DISCOVERY RULING NO. 14, PART 5, REGARDING
PRIVILEGE AND CARDINAL’S DENDRITE AUDIT**

Introduction

As a distributor of controlled substances, Cardinal Health (“Cardinal”) has a duty to create and maintain a suspicious order monitoring system (“SOMS”) to prevent diversion. “Information regarding SOMS is central to Plaintiffs’ case against Cardinal.”¹ However, Cardinal has repeatedly cloaked, under improper claims of privilege, documents which reveal details of its SOMS.² The instant matter involves Cardinal’s privilege over-designation tactics relative to work done by one of its third-party regulatory consultants – Cegedim/Dendrite (“Dendrite”).

In late 2007, Dendrite was hired as an “independent third-party” to perform regulatory consultant services for Cardinal, including to: identify SOMS deficiencies; recommend and assist with SOMS improvements; perform on-site pharmacy-client inspections, train Cardinal employees on SOMS; and appease the DEA by showing that Cardinal was making substantive improvements to its SOMS. A necessary and integral part of this work included Dendrite

¹ Doc. #: 1428 at p. 2.

² Cardinal has made more than fifty-thousand (50,000+) privilege claims in MDL 2804. In fact, complaints of Cardinal’s over-designation of documents as privileged resulted in the Court ordering Defendants to limit privilege claims relative to SOMS. *See* Doc. #: 1147, at p. 1, ¶1.

conducting an audit of Cardinal's SOMS – which was finalized in a January 23, 2008 audit report (“Dendrite Audit”).

Cardinal has hidden the Dendrite Audit, as well as other Dendrite-related documents, through improper claims of privilege and by other means.³ Cardinal attempts to mis-characterize and cloak the audit (and other Dendrite-related documents) as privileged work performed strictly for providing legal advice. However, Cardinal used Dendrite's audit and work primarily (if not exclusively) for investigation, support and modification of its SOMS business operations, so that it could meet its regulatory obligations. Thus, preventing any potential privilege over the Dendrite Audit. “The privilege does not permit an attorney to conduct his client's business affairs in secret”.⁴ Further, any potential privilege which could attach to the Dendrite Audit has been waived by Cardinal's affirmative claims that it always complied with all relevant statutes and regulations. The Dendrite Audit reflects directly on Cardinal's affirmative claims regarding regulatory compliance, and the law does not allow Cardinal's use of privilege as a shield and a sword.

Procedural Background

On March 31, 2019, the Special Master issued Discovery Ruling No. 14, Part 5 (“Ruling”), finding in relevant part that: 1) the January 2008 Audit Report performed for Cardinal by Dendrite was primarily done for business rather than legal purposes, and not entitled to privileged treatment (either as attorney-client privilege or the work product doctrine), and 2) Cardinal had waived any potential privilege over the January 2008 Audit Report by affirmatively

³ Even though the Dendrite Audit formed the foundation for Cardinal's most substantial SOMS revisions, and even though it was implicated by numerous discovery requests as well as the Court's 11/21/2018 Order (Doc. #: 1147), Cardinal did not notify Plaintiffs' of the audit, and did not at first list it on its privilege logs.

⁴ *Glazer v. Chase Home Finance LLC*, 2015 WL 12733394 at *4 (N.D. Ohio Aug. 5, 2015) (quoting *Leazure v. Apria Healthcare Inc.*, No. 1:09–CV–224, 2010 WL 3895727, at *1 (E.D. Tenn. Sept. 30, 2010); *In re Grand Jury Subpoenas*, 803 F.2d 493, 496 (9th Cir. 1986)).

claiming that its SOMS complied with all applicable statutory and regulatory requirements.⁵ On 4/8/2019 Cardinal filed an objection (“CAH Obj.”) to the Ruling.⁶ Plaintiffs hereby file this reply.

Factual Background

The Ruling sets forth extensive and well supported facts surrounding Dendrite’s work and January 2008 Audit relative to Cardinal’s SOMS.⁷ As many of the factual findings from the Ruling have been uncontradicted or ignored by Cardinal, the PEC will not re-hash everything therein. However, for context and ease of reference, some background and relevant facts are provided.

In November and December of 2007, and early January of 2008, the DEA issued Orders to Show Cause to revoke Cardinal’s registration for 4 of its distribution centers (“DCs”). *See* Ruling at p. 2. The DEA also issued Immediate Suspension Orders (“ISOs”) for 3 of these 4 DCs. *Id.* Cardinal worked with its attorneys at Cadwalader, Wickersham & Taft LLP (“Cadwalader”) to respond quickly to the DEA’s 2007 actions. *Id.* at pp. 2-3. Shortly thereafter, Cadwalader hired Dendrite as a third-party regulatory compliance consultant for Cardinal. *Id.* at p. 3. The following is a timeline of some pertinent facts relative to Dendrite’s work and January 2008 Audit regarding Cardinal’s SOMS:

- On 12/5/2007, Cadwalader hired Dendrite “**to assist with regulatory compliance consulting to Cardinal Health**”, and the engagement agreement covered *all* of the work (including the audit and other clearly non-privileged work) which Dendrite did for Cardinal during the months surrounding the audit. *See* Ruling at pp. 2, 15.
- On 12/14-15/2007, **Dendrite emailed Cardinal addressing the scope of its work – laying out the true substantive/operational (non-legal) nature of its audit**, and stating it will include “onsite review of Cardinals suspicious order

⁵ Doc. #: 1498 at pp. 16-19.

⁶ Doc. #: 1530.

⁷ Ruling (Doc. #: 1498) at pp. 2-8, & 13-17.

monitoring program/system including verification of the system's operational effectiveness, system integrity, and regulatory suitability" (i.e., the audit), and that the recommendations from the audit "*will allow Cardinal to properly identify orders of unusual size, orders deviating substantially from normal pattern, and orders of unusual frequencies*". See Ex. 1 at p. 1.

- On 12/18/2007, Cardinal's Chief Legal Officer (Ivan Fong) sent a letter to the DEA with the clear goal of appeasing the DEA and limiting implementation of ISOs. See Ex. 8. The letter stated how **Cardinal was investigating its own distribution centers by having Dendrite conduct an "intensive onsite third-party review", with the intent of making the results available to the DEA.** *Id.* at p. 3. The letter also attached a 12/18/2007 Cardinal "Outline of Key Actions on Anti-Diversion" – which, among other things: a) **represented Dendrite as an "independent third-party"** responsible for various Cardinal SOMS responsibilities (including the audit at issue), and b) stated that Cardinal would "[d]evelop [a] corrective action plan and implement improvements **arising out of [the] independent third-party investigation**" (i.e., the audit at issue). *Id.* at pp. 5-6 (emphasis added).
- On 12/31/2007, Dendrite sent its initial invoice (directly to Cardinal) for all work it was doing, including the audit work. While Cardinal argues that Dendrite was retained by and working for outside counsel, the fact remains that **Dendrite was direct billing Cardinal, while simultaneous offers were being made by counsel to share the results of Dendrite's audits with the DEA.** Moreover, the itemization in Dendrite's invoice shows that it was providing substantive regulatory consulting and services directly to Cardinal. See Ex. 9.
- On 1/8/2008, an internal Cardinal email was sent stating in pertinent part that: "[i]t has been decided that **the Dendrite expenses and Litigation expenses related to the anti-diversion matter will be retained within the QRA [Quality & Regulatory Affairs] corporate function.** This was a decision by Jeff H [Jeff Henderson – Cardinal Chief Financial Officer] based on a commitment he made to the DEA." See Ex. 10 (emphasis added). The QRA Department was responsible for and had final say so over Cardinal's SOMS program. See Ex. 10a at p. 1.
- On 1/10/2008, Cardinal's Director of QRA (Carolyn McPherson) sent an email to many Cardinal employees regarding "Suspicious Order Monitoring System Auditing". In pertinent part, the email stated: "I wanted to give everyone a heads-up that **we have engaged an outside consulting firm Dendrite to assist in a validation (audit and testing activities) of the SOM system. [] This activity will obviously be an important part of the roll out of this system both internally and to be able to provide DEA with proof of the effectiveness of our processes.**" See Ex. 3 (emphasis added).

- On 1/14/2008, Cardinal's counsel (Jodi Avergun) sent another letter to the DEA advocating for limited implementation of ISOs for various Cardinal DCs. As support for same, this letter updated the DEA regarding Dendrite's "intensive onsite third-party review of [Cardinal's] distribution centers," and **again offered to share with the DEA the results of Dendrite's audit.** See Ex. 11 at p. 3.

In late January 2008 the "Dendrite Audit" was issued - allowing Cardinal to continue working toward its business needs (and promise to the DEA) to "[d]evelop [a] corrective action plan and implement improvements arising out of [its] independent third-party investigation". And, Dendrite went on to assist Cardinal with the design and implementation of an improved SOMS.

Legal Standards – Burden of Proof & Narrow Construction of Privilege

It is well established in the Sixth Circuit (and it has been undisputed by Cardinal) that: 1) the burden of establishing a privilege falls upon the party asserting it,⁸ and 2) privileges are to be narrowly construed.⁹ Moreover, these burden of proof and narrow construction standards have even greater meaning in the context of the current objection because of the Court's prior Order regarding invoking of privilege claims relative to SOMS details.

⁸ *United States v. Dakota*, 197 F.3d 821, 825 (6th Cir.2000) ("The burden of establishing the existence of the privilege rests with the person asserting it."). See also, *Davis v. Drake*, 2014 WL 5795554, at *4 (N.D. Ohio Nov. 6, 2014) ("The party claiming an attorney-client privilege not only bears the burden of proving that the privilege applies, but must also show that the privilege has not been waived."); *Amway Corp. v. Proctor & Gamble Co.*, 2001 WL 1818698, at *4 (W.D. Mich. Apr. 3, 2001) ("The risk of non-persuasion arising from a failure to establish facts supporting a claim of privilege falls upon the party asserting it.").

⁹ "Claims of attorney-client privilege are 'narrowly construed because [the privilege] reduces the amount of information discoverable during the course of a lawsuit.'" *In Re Columbia/HCA Healthcare Corporate Billing Practices*, 293 F.3d 289, 294 (6th Cir.2002) (quoting *United States v. Collis*, 128 F.3d 313, 320 (6th Cir.1997)). "The privilege cannot stand in the face of countervailing law or strong public policy and should be strictly confined within the narrowest possible limits underlying its purpose." *United States v. Skeddle*, 989 F. Supp. 890, 900 (N.D. Ohio 1997) (citing *United States v. Goldberger & Dubin, P.C.*, 935 F.2d 501, 504 (2nd Cir.1991)).

On November 21, 2018, the Court entered an order which required in pertinent part that “Defendants shall not interpose attorney-client privilege as a reason for not producing discovery of all details of their SOMS. The Court will not allow defendants to rely at trial, in any motion, or for any other reason, upon any evidence of the existence or method of operation of a SOMS that is not produced by this date.” *See* Doc. #: 1147, at p. 1, ¶1. Although this Order has not been interpreted by the Special Master as wholly precluding the application of privilege, it has been interpreted to mean that privilege invocation with regards to SOMS is “dicey” and that SOM-related privilege claims should be construed “extremely narrowly”.¹⁰

Law and Argument

There exist multiple independent legal and factual bases for why the Dendrite Audit is not entitled to privileged treatment, including but not limited to: a) Cardinal has failed to carry its burden of proving that the “primary purpose” of the Dendrite Audit was to provide legal advice as opposed to business/regulatory advice, b) third-party involvement (of Dendrite) destroys the privilege as Cardinal has not meet its burden of proving that the Dendrite Audit was indispensable for providing legal advice, that the audit was interpretive, and that the audit was for legal rather than business advice, and c) Cardinal has failed to carry its burden of proving that it did not waive any potential privilege. Any of these reasons is a basis for why the Dendrite Audit is not privileged.

A. Cardinal Failed to Meet Its Burden of Proving that Legal Advice was the Primary Purpose of the Dendrite Audit.

In order to meet its burden, the proponent of a privilege claim must prove that the “dominant intent” of the communication was to seek or provide “legal” rather than business

¹⁰ *See* transcript of 12/6/2018 discovery teleconference at 22:5-10.

advice. *In re Behr Dayton Thermal Products, LLC*, 298 F.R.D. 369, 375 (S.D. Ohio 2013). A “communication is not privileged simply because it is made by or to a person who happens to be an attorney. To be privileged, the communication must have the primary purpose of soliciting legal, rather than business, advice.” *Zigler v. Allstate Ins. Co.*, 2007 WL 1087607 at *1 (N.D. Ohio Apr. 9, 2007) (internal quotation marks and citations omitted, emphasis in original). Regulatory compliance advice is not legal advice.¹¹ Although Cardinal alleges that the Dendrite Audit was solely to provide legal advice, Plaintiffs have submitted substantial evidence proving that the primary purpose of the audit was for the business matter of regulatory compliance.

First, the 12/5/2007 engagement agreement with Dendrite explicitly states that Dendrite was hired “to assist with regulatory compliance consulting to Cardinal Health”, and nothing in the agreement distinguishes the audit work from any of the other non-legal work which Dendrite performed. *See* Ruling at p. 2. **Second**, Dendrite subsequently confirmed its scope of work, to include the audit work, as being performed for the operational business purpose of “allow[ing] Cardinal to properly identify orders of unusual size, orders deviating substantially from normal pattern, and orders of unusual frequencies”. *See* Ex. 1 at p. 1. **Third**, Dendrite directly billed Cardinal for its compliance work, including for the audit work as well as all other clearly non-privileged work, and Cardinal made payments for and categorized all such Dendrite work together - as a “QRA [Quality & Regulatory Affairs] corporate function”.¹²

¹¹ The attorney-client privilege does not extend to “communications made to secure or provide environmental [regulatory] advice...”. *Intl. Brotherhood of Elec. Workers Loc. 212 v. American Laundry Machinery, Inc.*, No. 07-cv-324, 2009 WL 81114, at *3 (S.D. Ohio Jan. 9, 2009). The privilege “does not apply if the client seeks regulatory advice for a business purpose.” *FTC v. Abbvie, Inc.*, 2015 WL 8623076 (E.D. Pa. Dec. 14, 2015). “Human resources work, like other business activities with a regulatory flavor, is part of the day-to-day operation of a business; it is not a privileged legal activity.” *Koumoulis v. Independent Financial Marketing Group, Inc.*, 29 F. Supp. 3d 142, 146 (E.D.N.Y. 2014).

¹² *See* Exs. 9, 10 & 10a. Categorizing the Dendrite consulting service as a business expense, rather than litigation expense, is a predicate act commonly used by registrants to use the expense as an offset to an

Fourth, an internal Cardinal email specifically states that the Dendrite Audit was being performed for the purposes of “the roll out of this [enhanced SOM] system both internally and to be able to provide DEA with proof of the effectiveness of our processes.” *See* Ex. 3. **Fifth**, Cardinal represented to the DEA that the Dendrite Audit was an “independent third-party” audit, and that it was being used by Cardinal for a operational business purpose - to “[d]evelop [a] corrective action plan and implement improvements arising out of [the] independent third-party investigation”. *See* Ex. 8 at pp. 3 & 5-6. **Sixth**, Cardinal repeatedly offered to share with the DEA the results of the Dendrite Audit. *Id.* at p. 3. *See also*, Ex. 11 at p. 3.

B. Cardinal Failed to Carry its Burden of Proving that the Dendrite Audit was “Nearly Indispensable” for Providing Legal Advice, that the Audit was Interpretive, and that the Audit was for Legal Rather than Business Advice.

“The attorney-client privilege is waived by voluntary disclosure of private communications by an individual or corporation to third parties.” *Dakota*, 197 F.3d at 825-26. An exception to this waiver rule exists for third parties employed to assist a lawyer in rendering legal advice. However, the proponent of the privilege must prove that involvement of the third party with client communications was: 1) “nearly indispensable” for the provision of legal advice, 2) to interpret information for the attorney, and 3) primarily for legal as opposed to business advice. While Cardinal has the burden of proving all three factors, it has failed to do so.

1. Cardinal failed to carry its burden of proving that the Dendrite Audit was “nearly indispensable” for the provision of legal advice.

“[T]hird-party communications must be ‘necessary, or at least highly useful, for the effective consultation between the client and the lawyer which the privilege is designed to permit.’” *Cavallaro v. United States*, 284 F.3d 236, 247–48 (1st Cir.2002) (quoting *United States v. Kovel*, 296 F.2d 918, 922 (2d Cir.1961)). “[T]he ‘necessity’ element means more than

administrative fine (rather than legal expense). Cardinal’s accounting of all Dendrite services as a component of QRA further proves its “business” status.

just useful and convenient.” *Id.* at 249. “The involvement of the third party must be nearly indispensable or serve some specialized purpose in facilitating the attorney-client communications.” *Id.* Plaintiffs have seen no evidence from Cardinal addressing this requirement.

2. Cardinal failed to carry its burden of proving that Dendrite was serving in an interpretive role.

Another requirement for the exception to third party waiver is that “the exception applies only to communications in which the third party plays an interpretive role.” *Dahl v. Bain Capital Partners, LLC*, 714 F.Supp.2d 225, 228 (D.Mass.2010). “In other words, the third party’s communication must serve to translate information between the client and the attorney.” *Id.* See, e.g., *United States v. Ackert*, 169 F.3d 136, 139-40 (2d Cir.1999) (no exception when “[lawyer] was not relying on [3rd party] to translate or interpret information given to [lawyer] by his client.”). “[T]he attorney-client privilege can attach to reports of third parties made at the request of the attorney or the client **where the purpose of the report was to put in usable form information obtained from the client.**” *U.S. Postal Serv. v. Phelps Dodge Ref. Corp.*, 852 F. Supp. 156, 161 (E.D.N.Y. 1994) (citation omitted, emphasis added). Plaintiffs have seen no evidence from Cardinal addressing this requirement.

3. Cardinal failed to carry its burden of proving that the Dendrite Audit was conducted primarily for legal rather than business advice.

Finally, the exception to third party waiver also requires that “the third party’s communication must be made for the purpose of rendering legal advice, rather than business advice.” *Dahl*, 714 F.Supp.2d at 228. “What is vital to the privilege is that the communication be made in confidence for the purpose of obtaining legal advice from the lawyer. **If what is**

sought is not legal advice but only accounting service, ... or if the advice sought is the accountant's rather than the lawyer's, no privilege exists.”¹³

Plaintiffs adopt and incorporate by reference the facts and reasons set forth in the “Factual Background” and in section A, *supra*. The primary purpose of the Dendrite Audit was to improve Cardinal’s SOMS, not primarily to assist counsel in providing legal advice. The advice from the audit sought by Cardinal was that of Dendrite’s, not counsels’ advice. Not coincidentally, Cardinal used the audit to: 1) attempt to convince the DEA that the Cardinal SOMS was being updated and strengthened, and 2) “[d]evelop [a] corrective action plan and implement improvements [to its SOMS] arising out of [the] independent third-party investigation”. *See* Ex. 8 at pp. 3 & 6.

C. Cardinal Failed to Carry its Burden of Proving it Has Not Waived Privilege Relative to the Dendrite Audit and Work.

As held in a seminal case from the Second Circuit, and often cited to by the Sixth Circuit, a party may not use a privilege “to prejudice his opponent’s case or to disclose some selected communications for self-serving purposes.” *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991).¹⁴ “Litigants cannot hide behind the privilege if they are relying on privileged communications to make their case” or, more simply, cannot use the privilege as “a shield and a sword.” *In re Lott*, 424 F.3d 446, 454 (6th Cir. 2005) (quoting *Bilzerian*, 926 F.2d at 1292).

¹³ *Kovel*, 296 F.2d at 922 (citations omitted, emphasis added); *see Arkwright Mut. Ins. Co. v. Nat’l Union Fire Ins. Co. of Pittsburgh, Pa.*, 1994 WL 58999 at *5 (6th Cir. 1994) (citing *Kovel* with approval).

¹⁴ Importantly, the defendant in *Bilzerian* argued that the evidence “he sought to introduce regarding his good faith attempt to comply with the securities laws would not have disclosed the content or even the existence of any privileged communications” *Bilzerian*, 926 F.2d at 1291. However, the 2nd Circuit concluded that an affirmative defense grounded in the defendant’s good faith belief “that he thought his actions were legal would have put his knowledge on the law and the basis for his understanding of what the law required in issue. His conversations with counsel regarding the legality of his schemes would have been directly relevant in determining the extent of his knowledge and, as a result, his intent.” *Id.* at 1292. Consequently, the plaintiff was entitled to discover those “at-issue” communications. *Id.* at 1293–94.

“[T]he privilege may be implicitly waived when defendant asserts a claim that in fairness requires examination of the protected communications.” *In re United Shore Financial Services, LLC*, 2018 WL 2283893 at *2 (6th Cir. Jan. 3, 2018) (quoting *Bilzerian*, 926 F.2d at 1292). “The waiver may be found even if the privilege holder does not attempt to make use of a privileged communication; he may waive the privilege if he makes factual assertions the truth of which can only be assessed by examination of the privileged communication.” *In re Kidder Peabody Securities. Litigation*, 168 F.R.D. 459, 470 (S.D.N.Y. 1996).¹⁵

Cardinal’s discovery responses and affirmative defenses assert that: a) Cardinal has always been (and believed it was) in full compliance with all applicable federal, state, and local statutes and regulations, and b) Cardinal’s extensive efforts and work over the years - including work with and by Dendrite and other third parties – has resulted in a “state-of-the-art” and compliant SOMS. Some examples of Cardinal’s discovery responses and affirmative defenses include:

Cardinal Health has **always intended and believed it was acting in compliance with the relevant statutes, regulations, and guidance that DEA provided** about what it expected distributors to do in order to be in compliance with same.¹⁶

Cardinal Health’s controlled substance monitoring program and scrutiny of its pharmacy customers **meets or exceeds all DEA requirements**.¹⁷

¹⁵ See also, *Scott v. Chipotle Mexican Grill, Inc.*, 2014 WL 7236907, at *8 (S.D.N.Y. Dec. 18, 2014) (“forfeiture of [] privilege may result where the proponent asserts a good faith belief in the lawfulness of its actions, even without expressly invoking counsel’s advice.”); *Regents of the Univ. of Cal. v. Micro Therapeutics, Inc.*, No. C-03-05669, 2007 WL 2069946, at *3 (N.D. Cal. July 13, 2007) (“Courts frequently conclude that a party waives the protection of the attorney-client privilege when the party voluntarily injects into suit a question that turns on state of mind.”); *Minebea Co. v. Papst*, 355 F.Supp.2d 518, 524 (D.D.C.2005) (“By putting reliance on Papst’s statements in issue, Minebea has opened the door to exploration by Papst of what other persons, documents and information Minebea relied on other than Papst.”); *Baker v. Gen. Motors Corp.*, 209 F.3d 1051, 1055 (8th Cir. 2000) (at-issue waiver is commonly found where “proof of a party’s legal contention implicates evidence encompassed in the contents of an attorney-client communication....”).

¹⁶ See Ex. 6 (Cardinal’s 11/30/2018 First Supplemental Objections and Responses to Plaintiffs’ First Combined Discovery Requests), at p. 8. (Emphasis added).

¹⁷ *Id.* at p. 9. (Emphasis added).

Cardinal Health has enhanced and evolved its system to ensure that it remains state-of-the-art, continues to comply with DEA guidance as that guidance has changed over time, and to adjust to other factors impacting the distribution of controlled substances.¹⁸

[T]he activities of Defendant alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards based on the state of knowledge at the relevant time(s) alleged in the Complaint.¹⁹

Defendant complied at all relevant times with all applicable laws, including all legal and regulatory duties.²⁰

These affirmative claims place at issue the details of Cardinal's SOMS compliance, and any documents showing same. The Ruling found that the Dendrite Audit "reflects directly and clearly on the truth of" Cardinal's affirmative claims regarding its regulatory compliance. *See* Ruling at p. 18. As such, any privilege or work product protection for the audit has been waived. *See New Phoenix Sunrise Corp. v. C.I.R.*, 408 F. App'x 908, 919 (6th Cir. 2010).

D. Cardinal's Objections are Meritless

Cardinal argues that the Ruling is "erroneous in five respects", and that it erred in: 1) "applying *Upjohn* and *Kovel*", 2) "focusing on the primary purpose of Dendrite's overall work, not the Report", 3) "finding that the Dendrite Report was not work product", 4) "suggesting Cardinal Health waived the privilege", and 5) "ordering the production of documents other than

¹⁸ *Id.* (Emphasis added). *See also*, at p. 13 –referencing SOMS work with Dendrite and other third parties.

¹⁹ *See* Ex. 7 (1/15/2019 Answer and Affirmative Defenses of Cardinal Health, Inc. (Doc. #: 1256)), p. 138, 54th Defense. (Emphasis added). *See also*, at pp. 139-40, 60th Defense ("Defendant is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing ... complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA, and the generally recognized state of the art in the industry at the time ...").

²⁰ *Id.* at pp. 142, 76th Defense. (Emphasis added).

the Report”.²¹ Each of Cardinal’s arguments fail for several reasons. Although Cardinal’s arguments are dispelled in sections A, B & C above, the following supplements Plaintiffs’ reply:

1. The Ruling correctly applied *Upjohn* and *Kovel*, as well as similar cases.

Cardinal’s objection sets forth an incomplete and/or inapplicable analysis of *Upjohn Co. v. United States*, 449 U.S. 383 (1981), and *United States v. Kovel*, 296 F.2d 918 (2d Cir. 1961).²² Cardinal also ignores other relevant cases (as well as the relevant facts cited by the Ruling) in arguing that the Ruling erred in its application of the law relative to whether privilege attaches to documents or communications involving third party consultants.²³ Plaintiffs submit that a more thorough analysis, including the relevant requirements and applicable facts, is set forth in section B, *supra*, which is hereby adopted and incorporated by reference.

2. The Ruling properly focused on Dendrite’s audit work, as well as (for full context) the other work Dendrite performed for Cardinal.

Cardinal claims that “rather than evaluating the primary purpose of the Report, [the special master] evaluated the primary purpose of the overall *relationship* between Cardinal Health and Dendrite.” *See* CAH Obj. at p. 5 (emphasis in original). Cardinal’s claim is simply untrue and ignores various parts of the Ruling. The special master evaluated the primary purpose of *both* the Dendrite Audit and, for full context, the contemporaneous work Dendrite performed for Cardinal.

²¹ CAH Obj. at pp. 4-13.

²² *Id.* at pp. 4-5. *Upjohn* does not address communications involving third party consultants, and cannot be fully applied to the Dendrite Audit. 449 U.S. at 390. Also, Cardinal fails to provide the most applicable quotation from *Kovel* (“If what is sought is not legal advice but only [consulting] service, ... or if the advice sought is the [consultant’s] rather than the lawyer’s, no privilege exists.”). 296 F.2d at 922.

²³ CAH Obj. at pp. 4-5. For example, Cardinal ignores the Ruling’s application of analogous cases, including *Occidental Chem. Corp. v. OHM Remediation Servs. Corp.*, 175 F.R.D. 431, 437 (W.D.N.Y. 1997) (holding privilege did not apply where counsel hired an environmental consultant to formulate a remediation plan, and not “specifically to assist them in rendering legal advice;”). *See* Ruling at p. 17.

Based upon extensive evidence, the Ruling repeatedly and specifically found that the primary (if not exclusive) purpose of the Dendrite Audit was to identify and execute modifications necessary to improve Cardinal's SOMS and regulatory compliance. *See e.g.*, Ruling at pp. 7 & 16-17. The Ruling further found that "Dendrite did go on to assist Cardinal with the design and implementation of a new and improved Suspicious Order Monitoring System", which of course required the foundational work of the Dendrite Audit. *Id.* at pp. 7-8. While the Ruling also analyzed the other work Dendrite was performing for Cardinal at the time of the audit, such analysis simply provided further context of the true business purpose of the audit.²⁴

3. The Ruling correctly found that the audit was not protected work product.

Relative to the work product doctrine, "the burden is on the party claiming protection to show that anticipated litigation was the **driving force** behind the preparation of each requested document."²⁵ Even where a document "might also help in preparation for litigation," it will not be protected as work product if it was "prepared in the ordinary course of business or pursuant to regulatory requirements", or "would have been created in essentially similar form irrespective of the litigation."²⁶ The Dendrite Audit was prepared primarily as part of Cardinal's ordinary

²⁴ The evaluation of all work that Dendrite was performing for Cardinal (at the time of the audit) provided important supplemental facts, just some of which include: a) Dendrite confirmed with Cardinal that its overall scope of work included the audit and that the work would allow Cardinal to modify and strengthen its SOMS, b) Dendrite directly billed Cardinal for its work, combining the audit work with all other clearly non-privileged work, and c) Cardinal made payments for and categorized all of Dendrite's work (including the audit work) together - as a "QRA corporate function". *See* section A, *supra*.

²⁵ *In re: Professional's Direct Ins. Co.*, 578 F.3d 432, 438 (6th Cir. 2009) (internal quotation marks and citations omitted, emphasis added).

²⁶ *Shinnecock Indian Nation v. Kempthorne*, 652 F.Supp.2d 345, 362 (E.D.N.Y.2009) (quoting *State of Maine v. U.S. Dep't of the Interior*, 298 F.3d 60, 69 (1st Cir.2002)). *See also*, *National Union Fire Ins. Co. v. Murray Sheet Metal Co., Inc.*, 967 F.2d 980, 984 (4th Cir.1992) ("materials prepared in the ordinary course of business or pursuant to regulatory requirements or for other non-litigation purposes are not documents prepared in anticipation of litigation within the meaning of Rule 26(b)(3)").

business and pursuant to regulatory requirements.²⁷ As such, the audit is not work product in the first place, and the Ruling correctly found same. *See* Ruling at pp. 16-17.

Even if the Dendrite Audit was work product, the Ruling also found it to be discoverable pursuant to Fed. R. Civ. P. 26(b)(3)(A) and the extensive analysis/findings previously made (by the special master and the Court) regarding Plaintiffs’ “substantial need” for information regarding Cardinal’s SOMS.²⁸ Cardinal claims that the Ruling improperly relied on these prior findings because they “involved different documents” than the Dendrite Audit. However, Cardinal’s objection ignores the fact that the Dendrite Audit involves the same subject (SOMS details) as the documents at issue in Amended Discovery Ruling 14, Part 1 (“ADR 14-1”) and the Court’s Order upholding same.²⁹ It is no surprise the Ruling found that “[t]he analysis of the two Cardinal charts [from ADR 14-1] applies even more strongly to the Dendrite Audit”. *See* Ruling at p. 18.

4. The Ruling correctly found that Cardinal waived any potential privilege.

Cardinal’s argument alleging error with the Ruling, relative to waiver, is a new argument not previously made by Cardinal before the special master.³⁰ This portion of the CAH Obj. should be stricken. Regarding the substance of Cardinal’s “at issue” or subject matter waiver, Plaintiffs adopt and incorporate by reference the law, facts and analysis set forth in section C, *supra*.

²⁷ *See* Factual Background and section A, *supra*. *See also*, Ruling at pp. 7 & 16-17.

²⁸ *See* Amended Discovery Ruling 14, Part 1 (Doc. #: 1380) at pp. 4-6; Order (Doc. #: 1428) at pp. 2-3, which are incorporated by reference herein.

²⁹ *Id.*

³⁰ This violates the Court’s 2/8/2019 Order which stated in pertinent part that “going forward, the Court will strike any party’s objection to a special master’s ruling that raises, for the first time before the Court, new evidence or legal theories not first provided to the special master for consideration. *See* Doc. #: 1344 at p. 2. Plaintiffs’ submission arguing “at issue” and/or subject matter waiver was made to the special master (with a copy to counsel for Cardinal) on February 15, 2019. Cardinal did not counter this argument for more than a month, and then the Ruling was made on March 31, 2019.

5. The Ruling properly ordered production of documents other than the audit.

Courts routinely apply privilege rulings over sample documents to other representative documents.³¹ Such a procedure is particularly warranted under the present scenario where the documents: a) involve third-parties, b) involve business/regulatory matters (SOMS), and c) can be objectively identified and categorized. And, Cardinal's over-designating of documents as privileged (50,000+ privilege claims), as well as its continued refusal to provide full details of its SOMS, provides even further support for the Ruling.

Finally, Cardinal ignores the facts that it still has the initial opportunity of determining which of its privilege claims (and underlying documents) fall under the Ruling, and that it has control and recourse if it believes a privilege claim or document is not properly impacted by the Ruling. If Cardinal is unsure about whether a document falls under the Ruling, it can first seek guidance from the special master (e.g., via *in camera* review) prior to producing same.

CONCLUSION

Based on the foregoing jurisprudence, reasoning, and argument, Cardinal's Objection to Discovery Ruling No. 14, Part 5 should be overruled.

³¹ See e.g., *Sidibe, et al. v. Sutter Health*, 12-cv-04854, 2018 WL 783808 *6 (N.D. Cal. Feb. 7, 2018) (ordering producing party to apply the ruling to future privilege discussions and disputes); *In re Chase Bank USA, N.A. Check Loan Contract Litigation*, Case No. 3:09-md-2032-MMC, 2011 WL 3268091 at *6 (N.D.Cal. July 28, 2011) (conducting in camera review of privilege as to 20 documents and ordering defendants to apply decisions the results to the remaining 2,870 disputed documents); *General Elec. Co. v. Johnson*, 2006 WL 2616187 *21 (D.C.C. Sept. 12, 2006) (ordering the party asserting privilege to apply determinations to other privilege claims). In fact, the Court has already allowed categorical privilege determinations in connection with Discovery Ruling 14, Part 3 (Doc #: 1359) and the common interest privilege. See 3/7/2019 Order (Doc. #: 1422) overruling objection to Discovery Ruling 14, Part 3.

Dated: April 12, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 12th day of April, 2019, I have electronically filed the foregoing with the Clerk of Court using the CM/ECF System. Copies will be served upon defense counsel via email.

s/Peter H. Weinberger

Peter H. Weinberger

Plaintiffs' Liaison Counsel